MEMO

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR VETERINARY MEDICINE

8483 '00 MAR 27 A11 :05

DATE: 3/22/00

FROM: Animal Scientist
Quality Assurance Support Staff, HFV-102

SUBJECT: Suitability Petition Response for Display.

TO: Lyle Jaffe, HFA-305, 5630 Fishers Lane, rm. 1061, Rockville, MD
Dockets Management Branch, 301 827-6860 (V)

The attachment is the Center for Veterinary Medicine's letter related to Suitability Petition **SP 00P-0444 CP1**, Phoenix Scientific filed as a **Suitability Petition**. We are forwarding a copy for public display with the petition.

If you have any questions, please call me at 827-0211, or FAX 594-2297.

Thank you.

03/22/00

Sam Hansard, Ph.D.

Attachment

Samuel Hansard, Ph.D.
FDA/CVM/ONADE/QASS/HFV-102
7500 Standish Place MPN II 384
Rockville, MD 20855
(301) 827-0211
(301) 594-2297 fax
shansard@cvm.fda.gov

00P-0444

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

8484 '00 MAR 27 A11 :05

MAR 22 2000

SP 00P-0444/CP 1

Robert D. Gunderson
Vice President
Regulatory Affairs
Phoenix Scientific, Inc.
St. Joseph, MO 64503

Dear Mr. Gunderson:

We refer to your suitability petition filed February 4, 2000, in which you requested permission to submit an abbreviated new animal drug application (ANADA) for a generic product with an active ingredient that differs from that of an approved new animal drug. The pioneer product is a tablet containing spectinomycin sulfate tetrahydrate; whereas your proposed product is a tablet containing spectinomycin dihydrochloride pentahydrate. The proposed pioneer product is Pharmacia & Upjohn's Adspec® Sterile Solution (spectinomycin sulfate tetrahydrate) which is intended for use in cattle (NADA 141-077).

FDA considers a salt or ester of an active ingredient to be a different active ingredient, and will not approve petitions that seek permission to submit an ANADA for a drug product which substitutes a different salt or ester for an active ingredient from that of a listed drug, unless the petition seeks a change in a combination product and the new salt or ester has been approved or is not a new animal drug. Hence, the petition is denied, and a new animal drug application (NADA) would be required for approval.

If you disagree with our denial of your suitability petition, you may petition for reconsideration of the denial following the procedures set forth in 21 CFR 10.33. Such a petition is based solely on the information and views contained in your original petition and is submitted in accordance with § 10.20 in the format outlined in § 10.33. The petition for reconsideration is submitted no later than 30 days after the date of this denial of the suitability petition, and should be filed with the Dockets Management Branch, Food and Drug Administration, HFA-305, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please refer to the docket number cited above in any submission regarding this original suitability petition.

If there is additional information not included as part of your original submission that you would like the agency to consider, you should submit a new petition including all the necessary information, to the Dockets Management Branch at the address noted above.

You may contact Dr. Steven D. Vaughn, Director, Division of Therapeutic Drugs for Food Animals, (301) 827-7580, for any questions on the specific requirements for the NADA submission.

Sincerely yours,

Claire M. Lathers, Ph.D., F.C.P.
Director
Office of New Animal Drug Evaluation
Center for Veterinary Medicine